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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,705	12/10/2001	Valdemar Portney	L-1609	4429

7590 09/30/2004

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EXAMINER	
MILLER, CHERYL L	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,705	PORTNEY, VALDEMAR	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 28-35* is/are pending in the application.

4a) Of the above claim(s) *7-9 and 13-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,10-12,16-19 and 28-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 December 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

Claim 10 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 10 positively recites a portion of the body, which is non-statutory subject matter. Claim 10 recites, "said intraocular lens is implanted in an individual's capsular bag", the applicant is positively claiming the capsular bag. It is suggested to change "implanted" to --implantable--.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The language "disclosed" and "embodiment" is legal terminology and should be changed.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "50" has been used to designate both posterior surface and anterior surface. It is suggested on page 14 line 30 and on page 18 line 25 to change "posterior surface 50" to recite --anterior surface 50--. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Also, reference character "102" has been used to designate both notches on page 17 line 9 and posterior surface on page 17 line 16 and in the figures.

Also, it is suggested to change on page 16, line 1, "leg 42" to recite --leg 46--, in order to be consistent with the drawings.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 112, cited on page 18, line 22. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 100a, 100c, and

100d, seen in fig.15a, 15c, and 15d. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 10-12, 16-19, and 28-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Thompson (US 5,607,472). Referring to claim 1 (see fig.3a, 4), Thompson discloses an accommodating IOL (22) comprising a deformable elastic dynamic lens (23) having a surface curvature (curvature of anterior surface 33), a lens-shaping member (circumferential periphery 36 including channel 28) having flexible portions (walls of channel 28) in contact with

the dynamic lens (23) for enabling deformation of the dynamic lens for changing the surface curvature (col.6, lines 42-50), an elastically flexible member (wire in channel, col.5, lines 35-37) in contact with the lens-shaping member flexible portions (36+28) , and first (37, 38) and second (24) lens supporting members, the first lens supporting member (37, 38) having a proximal end region engaging the flexible member (wire, col.5, lines 35-37) and a distal end region, the second lens supporting member (24) having a proximal end region (top of 24) connected to the lens-shaping member (36+28) and distal end region (bottom), the distal end region of the first lens supporting member (top of 37, 38) being configured upon implantation to engage a first region of the individual's eye that is responsive to contraction and relaxation of a ciliary muscle disposed in a ciliary body region of the individual's eye.

Referring to claim 2, Thompson discloses a distal end region (bottom) of the second lens supporting member (24) configured to engage a second region of the eye (fig.4), the first and second regions generally centered on a single meridian that passes through an optical axis of the dynamic lens.

Referring to claim 3, Thompson discloses first (37, 38) and second (24) lens supporting members being relatively rigid (col.5, lines 12-15) as compared with the dynamic lens (23).

Referring to claim 4, Thompson discloses a proximal end region of the second lens supporting member (24) rigidly connected to the lens-shaping member (36+28; fig.3a, 4).

Referring to claim 5, Thompson discloses the lens-shaping member (36+28) and the second lens supporting member (24) constructed in one piece (they are attached, therefore, one piece, how they were manufactured is a method step, and irrelevant in this product claim).

Referring to claim 6, Thompson discloses a flexible member (wire; col.5, lines 35-37) comprising a coil (Thompson's disclosed wire, will coil around the lens 23) encircling the flexible portions of the lens-shaping member (walls of 36 and 28).

Referring to claims 10-12, Thompson discloses a lens (23) capable of being implanted into a capsular bag of the eye (fig.4), wherein the distal end regions of the first (37, 38) and second (24) lens supporting members are configured for attachment to the bag (fig.4) and wherein the flexible portions of the lens-shaping member (walls of 36 and 28) are responsive to increases and decreases in tension applied to the supporting members, thereby changing the diameter and surface curvature of the dynamic lens (col.6, lines 43-50).

Referring to claim 16, Thompson discloses a flexible member (wire/sprocket) comprising a shape memory metallic alloy (allows compression, expansion, therefore is a material with memory).

Referring to claims 17-18, Thompson discloses a dynamic lens comprising silicone or acrylic and a lens-shaping member and supporting members comprising PMMA (col.5, lines 12-15).

Referring to claim 19, Thompson discloses a second lens supporting member (24) including a static, non-accommodating lens having an optical axis aligned with an optical axis of the dynamic lens (fig.3a, 4; col.5, lines 9-12).

Referring to claim 28 (see fig.5), Thompson discloses an accommodating IOL (fig.5) comprising a dynamic lens (23) having an elastically deformable curved surface (anterior surface 33), a static haptic (flaps 37, 38) having a flexible portion in contact with the dynamic lens (23) and configured to engage upon implantation, a first region of the eye (see fig.5), an elastic

member (periphery 36+28, including wire or gel) in contact with the flexible portion of the static haptic (37, 38), and a dynamic haptic (47) coupled to the elastic member (36+28, including wire or gel) and configured to engage upon implantation, a second region of the eye (bottom of capsule) responsive to contraction and relaxation of a ciliary muscle of the eye, whereby the dynamic haptic (47) is configured upon implantation, to deform in response to contraction and relaxation of the ciliary muscle, thereby deforming the elastic member (36+28, including wire of gel) and the flexible portion of the static haptic (37, 38), and changing the curvature of the curved surface of the dynamic lens (col.6, lines 45-50).

Referring to claims 29-30 (see fig.3a, 4), Thompson discloses an accommodating IOL system (22) comprising a lens (23) having an elastically deformable curved surface (33), and a deformable spring (wire/sprocket; col.5, lines 35-37) coupled to the lens (23) and configured upon implantation, to respond to contraction and relaxation of a ciliary muscle of the eye by elastically changing the curvature of the curved surface (33) of the lens (23), and wherein the spring comprises a coil (wire/sprocket, coils around lens).

Referring to claim 31, Thompson discloses an accommodating IOL (22) comprising a lens (23) having a deformable surface (33), and first (37, 38) and second (wire/sprocket or gel; col.5, lines 35-37) members coupled together to transfer force form the ciliary muscle to the lens (23), the first member (37, 38) responsive to contractions of the ciliary muscle to apply a force to the second member (wire/sprocket or gel, col.5, lines 35-37) such that the second member is in tension, the second member applying a second force to the lens (23) in response to the tension such that the curvature changes (col.6, lines 45-50).

Referring to claim 32, Thompson discloses the second member (wire/sprocket or gel) to at least substantially surround a periphery of the lens (fig.3a, 4).

Referring to claim 33, Thompson discloses a support member (24) coupled to the lens, wherein the lens (23) has a first surface (posterior surface) with a first curvature and a second surface (anterior surface 33) with a second curvature, and wherein the support member (24) supports the lens (23) with the first curvature fixed while the second curvature changes in response to the tension (fig.3a, 4; col.5, lines 10-20).

Referring to claim 34, Thompson discloses a first member (37, 38) comprising a forked member that splays in response to contractions of the ciliary muscle and that provides the tension of the second member (wire/sprocket or gel).

Referring to claim 35, Thompson discloses the second member (wire/sprocket) to comprise a coil (will coil around the lens 23).

Claims 1-5, 17-19, 28-29, and 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Turley (US 4,892,543, cited by applicant in IDS). Referring to claim 1, Turley discloses an accommodating IOL (40) comprising a deformable elastic dynamic lens (84) having a surface curvature (curvature of 86), a lens-shaping member (54) having flexible portions (all of 54 is flexible) in contact with the dynamic lens (84) for enabling deformation of the dynamic lens for changing the surface curvature (curvature of 86 changes), an elastically flexible member (70, 72) in contact with the lens-shaping member (54) flexible portions, and first (60) and second (46) lens supporting members, the first lens supporting member (60) having a proximal end region (one side of 60) engaging the flexible member (70, 72) and a distal end region (other side

of 60), the second lens supporting member (46) having a proximal end region (one side of 46) connected to the lens-shaping member (54) and distal end region (other side of 46), the distal end region of the first lens supporting member (60) being configured upon implantation to engage a first region of the individual's eye (top of capsule or area near iris) that is responsive to contraction and relaxation of a ciliary muscle disposed in a ciliary body region of the individual's eye.

Referring to claim 2, Turley discloses a distal end region of the second lens supporting member (46) configured to engage a second region of the eye (bottom of capsule or near there), the first and second regions generally centered on a single meridian that passes through an optical axis of the dynamic lens (86).

Referring to claim 3, Turley discloses first (60) and second (46) lens supporting members being relatively rigid as compared with the dynamic lens (84), (Turley's lens 86 has a fluid filled chamber and is less rigid than all other solid parts within the IOL system).

Referring to claim 4, Turley discloses a proximal end region of the second lens supporting member (46) rigidly connected to the lens-shaping member (54; fig.2).

Referring to claim 5, Turley discloses the lens-shaping member (54) and the second lens supporting member (46) constructed in one piece (fig.2).

Referring to claims 17-18, Turley discloses a dynamic lens (84) comprising silicone or acrylic and a lens-shaping member (54) and supporting members (60, 46) comprising PMMA (col.3, lines 12-19).

Referring to claim 19, Turley discloses a second lens supporting member (46) including a static, non-accommodating lens having an optical axis aligned with an optical axis of the dynamic lens (fig.2, 4, 6).

Referring to claim 28, Turley discloses an accommodating IOL (40) comprising a dynamic lens (84) having an elastically deformable curved surface (86), a static haptic (54) having a flexible portion in contact with the dynamic lens and configured to engage upon implantation, a first region of the eye, an elastic member (80, 82) in contact with the flexible portion of the static haptic (54), and a dynamic haptic (70, 72) coupled to the elastic member (80, 82) and configured to engage upon implantation, a second region of the eye responsive to contraction and relaxation of a ciliary muscle of the eye, whereby the dynamic haptic (70, 72) is configured upon implantation, to deform in response to contraction and relaxation of the ciliary muscle, thereby deforming the elastic member (80, 82) and the flexible portion of the static haptic (54), and changing the curvature of the curved surface (86) of the dynamic lens (84).

Referring to claim 29, Turley discloses an accommodating IOL system (40) comprising a lens (84) having an elastically deformable curved surface (86), and a deformable spring (42 +70, 72) coupled to the lens (84) and configured upon implantation, to respond to contraction and relaxation of a ciliary muscle of the eye by elastically changing the curvature of the curved surface (86) of the lens (fig.2, 4, 6).

Referring to claim 31, Turley discloses an accommodating IOL (40) comprising a lens (84) having a deformable surface (86), and first (70, 72) and second (42) members coupled together to transfer force form the ciliary muscle to the lens (84), the first member (70, 72) responsive to contractions of the ciliary muscle to apply a force to the second member (42) such

that the second member is in tension, the second member applying a second force to the lens in response to the tension such that the curvature changes.

Referring to claim 32, Turley discloses the second member (42) to at least substantially surround a periphery of the lens (fig.2).

Referring to claim 33, Turley discloses a support member (60) coupled to the lens (84), wherein the lens (84) has a first surface (top anterior surface) with a first curvature and a second surface (86) with a second curvature, and wherein the support member (60) supports the lens with the first curvature (anterior surface) fixed while the second curvature (86) changes in response to the tension.

Referring to claim 34, Turley discloses a first member (70, 72) comprising a forked member (fig.3) that splays in response to contractions of the ciliary muscle and that provides the tension of the second member (42).

Claims 28-32 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Rizzo, III et al. (US 6,120,538). Referring to claim 28, Rizzo discloses an accommodating IOL comprising a dynamic lens (12) having an elastically deformable curved surface, a static haptic (right 26 in fig.1) having a flexible portion in contact with the dynamic lens (12) and configured to engage upon implantation, a first region of the eye, an elastic member (14) in contact with the flexible portion of the static haptic (right 26), and a dynamic haptic (left 26 in fig.1) coupled to the elastic member (14) and configured to engage upon implantation, a second region of the eye responsive to contraction and relaxation of a ciliary muscle of the eye, whereby the dynamic haptic (26) is configured upon implantation, to deform in response to contraction and relaxation

of the ciliary muscle, thereby deforming the elastic member (14) and the flexible portion of the static haptic (26), and changing the curvature of the curved surface of the dynamic lens (12; col.1, lines 39-47).

Referring to claims 29-30, Rizzo discloses an accommodating IOL system comprising a lens (12) having an elastically deformable curved surface, and a deformable spring (14) coupled to the lens (12) and configured upon implantation, to respond to contraction and relaxation of a ciliary muscle of the eye by elastically changing the curvature of the curved surface of the lens (col.1, lines 39-41), and wherein the spring comprises a coil (fig.1).

Referring to claim 31, Rizzo discloses an accommodating IOL comprising a lens (12) having a deformable surface, and first (26 or 20) and second (14) members coupled together to transfer force form the ciliary muscle to the lens (12), the first member (26 or 20) responsive to contractions of the ciliary muscle to apply a force to the second member (14) such that the second member (14) is in tension, the second member applying a second force to the lens (12) in response to the tension such that the curvature changes (col.1, lines 39-47; col.3, lines 15-34).

Referring to claim 32, Rizzo discloses the second member (14) to at least substantially surround a periphery of the lens (12; see fig.1).

Referring to claim 35, Rizzo discloses the second member (14) to comprise a coil (fig.1).

Claims 29-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Christie et al. (US 4,932,966). Referring to claims 29-30, Christie discloses an accommodating IOL system (fig.13) comprising a lens (48) having an elastically deformable curved surface (50), and a deformable spring (110) coupled to the lens (48) and configured upon implantation, to respond to

contraction and relaxation of a ciliary muscle of the eye by elastically changing the curvature of the curved surface (50) of the lens (48), and wherein the spring comprises a coil (110, fig.13).

Referring to claim 31, Christie discloses an accommodating IOL comprising a lens (48) having a deformable surface (50), and first (70) and second (110) members coupled together to transfer force form the ciliary muscle to the lens (48), the first member (70) responsive to contractions of the ciliary muscle to apply a force to the second member (110) such that the second member is in tension, the second member applying a second force to the lens in response to the tension such that the curvature changes.

Referring to claim 32, Christie discloses the second member (110) to at least substantially surround a periphery of the lens.

Referring to claim 33, Christie discloses a support member (36) coupled to the lens, wherein the lens has a first surface (posterior surface) with a first curvature and a second surface (anterior surface 50) with a second curvature, and wherein the support member (36) supports the lens (48) with the first curvature fixed (fig.7, 13) while the second curvature (50) changes in response to the tension.

Referring to claim 35, Christie discloses the second member (110) to comprise a coil (fig.13).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cheryl Miller

BRUCE SNOW
PRIMARY EXAMINER